

SECTION 5.0: 510(k) SUMMARY

5.1 MANUFACTURER / REGISTRATION INFORMATION

Lake Region Medical	Contact Person:	Mathew Pexa
340 Lake Hazeltine Drive	Title:	Regulatory Specialist II
Chaska, MN 55318-1029 USA	Telephone:	952-641-8511
FDA REGISTRATION NUMBER: 2126666	Fax:	952-448-3441

5.2 TRADE NAME (PROPRIETARY NAME)

Pre-Formed Guidewire

5.3 DEVICE COMMON NAMES/USUAL NAMES/CLASSIFICATION NAMES

CATHETER GUIDEWIRE (DQX)

5.4 CLASS OF DEVICE

This type of Guidewire was originally listed as a Class II device by the Cardiovascular (DQX) review panel.

5.5 IDENTIFICATION OF PREDICATE DEVICE(s)

510(k) NUMBER	MANUFACTURER	DEVICE NAME
K930622	Boston Scientific	Amplatz SuperStiff Guidewire

5.6 DEVICE DESCRIPTION

The 0.035" diameter, 260cm-300cm length guidewire is composed of two primary wire components: a core and a coil. Both components are made of stainless steel per ASTM A313. The core wire is a stainless steel wire which forms the inner body of the guidewire. The coil component is the guidewire's outer layer and is a stainless steel wire coated in Green Polytetrafluoroethylene (PTFE). The coil and core components are weld together on the distal and proximal ends, forming the guidewire. The distal end of the guidewire contains a double-curve.

OUTSIDE DIAMETER:	0.035"
LENGTHS:	260cm – 300cm
TIP SHAPE:	Double-curve
TIP SIZES:	Small - Large

5.7 COMPLIANCE WITH APPLICABLE STANDARDS

The guidewire is in compliance with ISO 10993-1, ISO 10993-4, ISO 10993-5, ISO 10993-7, ISO 10993-10, ISO 10993-11, ISO 10993-12, ISO 15223-1, EN 980, ISO 11135-1, and ISO 11070.

AUG 23 2013

SECTION 5.0: 510(k) SUMMARY**5.8 INTENDED USE STATEMENT**

The Pre-Formed guidewires are intended to facilitate the introduction and placement of interventional devices within the chambers of the heart, including those used within transcatheter aortic valve procedures.

5.8 CONTRAINDICATIONS

This wire is not intended for use in the cerebrovasculature or coronary arteries.

5.9 COMPARISON

Comparison bench and animal tests were completed on the Boston Scientific Amplatz SuperStiff guidewire with 510(k) number K930622 to determine substantial equivalence.

5.10 QUALIFICATION TESTING

The conclusions drawn from bench testing, biocompatibility, and a GLP animal study demonstrate the device is as safe, as effective and performs at least as safely and effectively as the legally marketed device.

BENCH TESTING

In order to demonstrate equivalence of the guidewire, Lake Region Medical performed testing to establish requirements. Test pieces were tested and inspected according to established requirements for visual/tactile, dimensional and mechanical attributes. Test methods were developed using *FDA Coronary and Cerebrovascular Guidewire guidance* and *ISO 11070:1998*. The following table lists the applicable bench tests performed at baseline and aging include:

- | | |
|-----------------------------------|----------------------------|
| • Dimensional | • ISO Visual |
| • FDA Device Compatibility | • ISO Fracture |
| • FDA Tensile Strength | • ISO Flex |
| • FDA Tip Flexibility | • ISO Corrosion Resistance |
| • FDA Coating Adherence/Integrity | • ISO Strength of Union |
| • FDA Catheter Compatibility | • ISO Radiopacity |
| • Packaging Study | • Body Stiffness |
| • Particulate | |

BIOCOMPATIBILITY TESTING

Biocompatibility testing per ISO 10993 series has been performed on the Pre-Formed guidewires and has been found to be acceptable.

- | | |
|--|---|
| • Cytotoxicity | • Lee and White Coagulation |
| • Kligman Maximization Test | • Unactivated Thromboplastin Time Assay |
| • Irritation / Intracutaneous Reactivity | • Acute Systemic Toxicity Test |
| • Complement Activation Assay | • Partial Thromboplastin Time Assay |
| • Rabbit Pyrogen | • USP Physicochemical Test |
| • Hemolysis | • Inhibition and Enhancement |
| • Thrombogenicity | |

ANIMAL STUDIES

A GLP Animal Study was completed to evaluate customer feedback, performance and safety of the Guidewire compared to the currently marketed device. The studies show the guidewires are substantially equivalent to the legally marketed device.

5.11 SUBSTANTIAL EQUIVALENCE DATA

The Pre-Formed guidewires are substantially equivalent to the Amplatz SuperStiff Guidewire manufactured by Boston Scientific cleared under 510(k) number K930622.

The guidewire has similar technological characteristics to the predicate device. The technological differences between the proposed device and the predicate device are:

- Larger Proximal Core Diameter
- Longer Distal Grind
- Lack of intermediate joint
- Stainless steel weld (as opposed to Solder)
- Double Curve on distal tip
- Lack of moveable core

The data generated by accepted test methods and comparisons to the predicate device show that the Pre-Formed guidewire is substantially equivalent to the predicate device and the technological differences listed above do not pose any new issues of safety or effectiveness.

The Pre-Formed guidewires are substantially equivalent to the Amplatz SuperStiff Guidewire cleared under 510(k) K930622. All test results support the claim of substantial equivalence.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-6609
Silver Spring, MD 20993-002

August 23, 2013

Lake Region Medical
C/O Mr. Mathew Pexa
Regulatory Specialist II
340 Lake Hazeltine Drive
Chaska, MN 55318-1029

Re: K130798
Trade/Device Name: Pre-Formed Guidewires
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guidewire
Regulatory Class: Class II
Product Code: DQX
Dated: August 14, 2013
Received: August 14, 2013

Dear Mr. Pexa:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



for
Bram D. Zuckerman, Ph.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure



PRODUCT: PRE-FORMED GUIDEWIRE
SUBMISSION DATE: March 21, 2013
SUBMISSION TYPE: TRADITIONAL 510(k)

INDICATIONS FOR USE

510(k) NUMBER (IF KNOWN): K130798

DEVICE NAME: PRE-FORMED GUIDEWIRES

INDICATIONS FOR USE:

The Pre-Formed guidewires are intended to facilitate the introduction and placement of interventional devices within the chambers of the heart including those within transcatheter aortic valve procedures.

This guidewire is not intended for use in the cerebrovasculature or coronary arteries.

PRESCRIPTION **X**
USE
(Part 21 CFR 801 Subpart D)

AND/OR

OVER-THE-
COUNTER USE
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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M. G. Williams